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Lubert Stryer

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EXAMINER

CALAMITA, HEATHER

ART UNIT

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/886,055
Filing Date: June 22, 2001
Appellant(s): STRYER ET AL.

Robin L. Teskin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 15, 2006, appealing from the Office action mailed December 13, 2005.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

The PTOL form 326, from the Office Action mailed December 13, 2005, indicates claims 23-36 are rejected. This is a typographical error for which the Examiner apologizes. Claims 34-36 are withdrawn from consideration as not directed to the elected invention. Claim 24 was examined with respect to the originally elected SEQ ID NOs 55 and 56. As explained in the Office Action mailed December 13, 2005, claims 34-36 were not examined on their merits as these claims are drawn to 50, 100 and 200 SEQ ID NOs respectively, as per MPEP 803.04. Additionally, claim 24 was examined only with respect to SEQ ID NO: 55 and SEQ ID NO: 56, elected in the response filed March 16, 2004.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. The status of the claims is as discussed above.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

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The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krautwurst et al. (Cell, 1998) in view of Burford et al. (US 2004/0224314).

Krautwurst teaches the method steps of claim 23.

- (a) providing a representative class of n olfactory receptors or ligand-binding domains thereof (see p. 918 col. 2 paragraph 4);
- (b) measuring values X_1 to X_n representative of at least one activity of the one or more odorants selected from the group consisting of binding of the one or more odorants to the ligand-binding domain of at least one of the n olfactory receptors, activating at least one of the n olfactory receptors with the one or more odorants, and blocking at least one of the n olfactory receptors with the one or more odorants (see p. 919 col. 1 and col. 2 lines 1-11); and

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(c) generating a representation of sensory perception from the values X_1 to X_n ; wherein at least one of the n olfactory receptors has an amino acid sequence of (see p. 919 col. 2 last paragraph, p. 920 col. 1 and col. 2 and Figure 3).

With regard to claim 24, Krautwurst et al. teach at least one of the olfactory receptors specifically recognizes the odorant, and there are between 5 and 350 of the n olfactory receptors selected from the listed amino acid sequences (see Figure 3 and abstract, where pooled chimeric receptors are screened with 26 different odorants).

With regard to claim 25, Krautwurst et al. teach at least two different activities are measured to provide the values X_1 to X_n [see Figure 3 and legend, where the response to 26 different odorants (presence and absence) is measured].

With regard to claim 26, Krautwurst et al. teach each odorant receptor is expressed in cells, and the cells expressing each odorant receptor are located at an identifiable position (see p. 918 col. 2 last paragraph, p. 920 panel A Figure 2 legend).

With regard to claim 27, Krautwurst et al. teach at least one olfactory receptor is soluble, and binding of odorant to a ligand-binding domain of the soluble olfactory receptor is measured in solution (see p. 918 col. 1 paragraph 2, where the receptors are soluble in the cell before they are translocated to the plasma membrane).

With regard to claim 28, Krautwurst et al. teach at least one olfactory receptor is in solid state, and binding of odorant to a ligand-binding domain of the solid-state olfactory receptor is measured on a substrate (see p. 919 col. 1 first full paragraph lines 7-9, p. 920 col. 2 paragraph 2, p. 921 col. 1 lines 7-9 and Figure 4 legend).

With regard to claim 29, Krautwurst et al. teach the value measured for binding is above a preset limit for specific binding to olfactory receptors (see Figure 4 and legend, where the baseline calcium level is compared to the calcium levels after binding).

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With regard to claims 30 and 31, Krautwurst et al. teach the value measured for activating an olfactory receptor is derived from a signal selected from the group consisting of intracellular Ca^{2+} , CAMP and IP_3 (see p. 918 col. 2 paragraph 3 lines 1-19).

With regard to claim 32, Krautwurst et al. teach the value measured for blocking an olfactory receptor is at least a reduction in binding of the odorant or activation by the odorant (see p. 919 col. 2 paragraph 2 lines 12-16, where desensitization is a reduction in activation of the signaling system when the odorant binds).

With regard to claim 33, Krautwurst et al. teach the sensory perception is generated with a neural network (see the abstract, where HEK-293 cells are transfected with chimeric receptors found on neurons, therefore this meets the claim limitation).

Krautwurst et al. do not teach SEQ ID NOs 55 and 56.

Burford et al. teach SEQ ID NOs 55 and 56 (see SEQ ID NOs 27 and 66 respectively as well as the attached alignments).

It would have been prima facie obvious to utilize the method as taught by Krautwurst et al. with the sequences as taught by Burford et al. since Burford et al. note “The largest subfamily of GPCRs, the olfactory receptors, are also members of the rhodopsin-like GPCR family. These receptors function by transducing odorant signals. Numerous distinct olfactory receptors are required to distinguish different odors. Each olfactory sensory neuron expresses only one type of olfactory receptor, and distinct spatial zones of neurons expressing distinct receptors are found in nasal passages. However, the expression of olfactory-like receptors is not confined to olfactory tissues (see p. 2 paragraph 0008).” An ordinary practitioner would have been motivated to use the method as taught by Krautwurst et al. with the sequences as taught by Burford et al. in order to assess the physiological functions of these receptors in the presence of a variety of odorants.

(10) Response to Argument

Prima Facie Case

In the rejection above Appellant does not dispute that Krautwurst et al. teach a method having all the steps as set forth in the instant claims except for the use of SEQ ID NO: 55 and SEQ ID NO: 56. Appellant further does not dispute that Burford et al. teach SEQ ID NO: 55 and SEQ ID NO: 56. The dispute centers on the combination of the two references.

Motivation

Two arguments can be made regarding the motivation to combine the references, the first being direct motivation and the second being the use of known equivalents.

Direct Motivation

As discussed in the rejection outlined above there is direct motivation to combine the references. Krautwurst teach a method of identifying ligands for olfactory receptors by expressing a receptor library. Krautwurst recognizes the value of large-scale identification of cognate-receptor-odorant interactions and Krautwurst discloses the advantages of expanding the number of olfactory receptors and odorants screened using the assay. Finally Krautwurst acknowledges efforts in other laboratories to elucidate the genomic organization and DNA sequences of olfactory receptors and these discoveries will be useful with his method of function analysis to increase number of examples of where the ligand recognition properties of the chimeric and full-length receptors can be examined (see p. 923 col. 2 lines 7-13). Clearly Krautwurst is motivated to use his method of analysis with other suspected olfactory receptors and ligands.

Burford discloses Appellants instantly claimed SEQ ID NO: 55 (and amino acid sequence) and SEQ ID NO: 66 (a DNA sequence encoding the amino acid sequence of SEQ ID NO: 55). Burford, discloses SEQ ID NO: 27 (Appellants SEQ ID NO: 55, an amino acid sequence) is an olfactory receptor at page 42 Table 3. Burford also discloses G-protein coupled receptors, polynucleotides which identify

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and encode them as well as methods of analysis (i.e. diagnosing, treating or preventing disorders associated with aberrant expression of these receptors). The largest subfamily of these receptors are the olfactory receptors and Burford recognizes the value in isolating and elucidating the amino acid and DNA sequences of the receptors for functional analysis.

As outlined in the rejection above, one of skill in the art would be motivated to combine the method of functional analysis, as taught by Krautwurst with the specific olfactory receptor sequences disclosed by Burford. A skilled artisan using the method of Krautwurst to study the olfactory receptors would be motivated to study the specific receptors disclosed by Burford because Krautwurst discloses the expectation that his method of analysis will be used to study olfactory receptors elucidated in other laboratories.

Equivalents

An argument of equivalence can also be made. MPEP 2144.08 II A. 4(c) states,

(c) Consider the Teachings of Structural Similarity Consider any teachings of a “typical,” “preferred,” or “optimum” species or subgenus within the disclosed genus. If such a species or subgenus is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214 (“Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.”). The utility of such properties will normally provide some motivation to make the claimed species or subgenus. Id.

Both Krautwurst and Burford disclose many olfactory receptors for analysis. One of skill in the art would be motivated to use alternative receptors with the method of analysis. In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established

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compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Applying this rule to the current situation, it is clear that instant SEQ ID NO: 55 and SEQ ID NO: 56 simply represent structural homologs, which are derived from a sequences suggested by the prior art as olfactory receptors and concerning which skilled artisan would attempt to obtain alternate compounds with improved properties, the claimed sequences are *prima facie* obvious over the cited references in the absence of secondary considerations.

Additionally, this is not an *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994) situation because the skilled artisan practicing the method of Krautwurst and looking for olfactory proteins with which to practice, would review Bulford and only be selecting from 24 olfactory receptors. While Bulford et al. teach 39 different amino acid sequences which are G-protein coupled receptors, only 24 are disclosed as olfactory receptors thus the disclosed genus is not so broad as to encompass a very large number of possibilities.

Secondary Considerations

No secondary considerations were raised by Appellant, so if the *prima facie* case is sufficient, the rejection should be maintained.

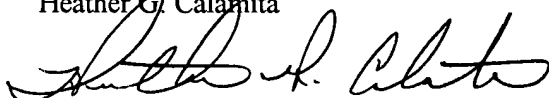
(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be maintained.

Respectfully submitted,

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